PROFESSIONAL INFORMATION

Scheduling Status: S0

1. Proprietary Name

Vitamin B Complex

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each white capsule contains	
Lynside®Forte B100 EU	225 mg
S. Cerevisiae enriched with B-Vitamins	
Of which	
Vitamin B1 (Thiamine HCl)	1.1 mg
Vitamin B2 (Riboflavin)	1.4 mg
Vitamin B3 (Nicotinamide)	15.3 mg
Vitamin B5 (D-Calcium Pantothenate)	5.7 mg
Vitamin B6 (Pyridoxine HCl)	1.5 mg
Vitamin B8 (Biotin)	49.5 ug
Vitamin B9 (Folic Acid)	202.5 ug
Vitamin B12 (Cyanocobalamin)	2.5 ug

2.2 Sugar Free.

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical Form

30 white size 0 capsules containing yellow coloured, free-flowing powder.

4. Clinical Information

4.1 Indications for Use

Indicated for individuals who may have a Vitamin B deficiency. May contribute to the protection of cells from oxidative stress, aid immune health and health maintenance, including nutritional support.

4.2 Method of Administration and Posology

4.2.1 Administration

Orally.

4.2.2 Posology

Adults and children over 18 only.

Take 1 capsule daily.

Take capsule with a sufficient quantity of water.

Do not chew the capsules swallow whole.

Take capsules at approximately the same time every day.

4.3 Contraindications

Not recommended for individuals who are hypersensitive (allergic) to any of the ingredients contained in the product.

4.4 Special Warnings and Precautions

Not recommended for individuals who are under the age of 18. Take **Vitamin B Complex** 2 hours before using other medication.

4.5 Interactions

S. Cerevisiae: Major risk of interaction with MAOIs. Moderate risk of interaction with antidiabetic drugs and lithium.

4.6 Pregnancy and Lactation

No known effects on pregnancy and breastfeeding.

4.7 Effects on ability to drive and use machinery.

None.

4.8 Side Effects

No known side effects.

5 Pharmacological Classification

Category D: 34.11 Vitamins.

Complementary Medicine.

6 Pharmacokinetic Properties

Absorption

Thiamine: the small intestine absorbs thiamine at the proximal part of the intestine. The mode of transport at smaller doses is by active transport and passive transport at higher doses.

Riboflavin: oral Riboflavin supplementation results in the production of 7-alpha-hydroxyriboflavin in blood plasma. The first order absorption rate constant was 1.2 hours, and peak concentrations of 40nM/L in males and 20nM/l in females within 2 hours. Increased GI motility is associated with decreased rate of absorption.

Nicotinamide: oral administration leads to dose dependant increase in blood NAD levels; therefore, nicotinamide riboside is bioavailable when taken orally. It takes 3 hours to maximum serum concentration.

Pyridoxine: Absorption occurs passively in the upper GI.

Biotin: absorption of biotin is complete after oral intake and reaches peak concentration after 1-2 hours. Passive diffusion takes place when extracellular levels of biotin exceed 25 mcM/L. After being cleaved it is transported across the intestinal lumen enterocytes by the SMVT (sodium-dependent multivitamin transporter and into the liver and peripheral tissue.

Folic Acid: synthetic Folate has a 100% availability.

Cyanocobalamin: Vitamin B12 is actively absorbed by binding with the intrinsic factor to be transported in the terminal ileum. In addition to the active absorption is 1.2% of vit B12 absorbed by passive diffusion. Maximum concentration occurs about 3 hours after oral supplementation.

Distribution

Thiamine: the distribution of thiamine is into the skeletal muscle, kidneys, liver, and brain.

Biotin: after absorption SMVT mediates biotin into both the liver and peripheral tissue.

Metabolism

Thiamine: metabolism is phosphorylated during intestinal uptake. Thiamine occurs as the metabolically active form thiamine diphosphate (TDP0).

Riboflavin: it is excreted in the urine

Nicotinamide: is converted to nicotinamide mononucleotide by the nicotinamide ribose kinase. These enzymes phosphorylate nicotinamide riboside, it is also converted to niacinamide by purine nucleoside phosphorylase. Nicotinamide riboside is also converted to niacinamide by intestinal bacteria.

Pyridoxine: B6 is converted to coenzyme pyridoxal phosphate in the liver.

Biotin: Biotin metabolites are formed by beta-oxidation, sulphur oxidation or even both.

Folic Acid: after folic acid is absorbed, it is reduced to tetrahydrofolate and then enters a methylation cycle. Unmetabolized folic acid is found in breast milk and in plasma after consumption.

Excretion

Thiamine: and its metabolites are excreted in the urine.

Nicotinamide: has a half-life of 2.7 hours.

Pyridoxine: excretion takes place in the urine.

Biotin: half of the Biotin dose is excreted within 24 hours in the urine as unmetabolized biotin.

Folic Acid: excreted in the urine; it may also be found in faeces.

Cyanocobalamin: The half-life is about 15 hours.

7. Pharmaceutical Information

7.1 List of Excipients

Vegetarian capsules, milled rice flour.

7.2 Incompatibilities

None noted.

7.3 Shelf Life

24 months from date of manufacture.

7.4 Storage

Store in a cool dry place, between 15°C-25°C. Store in original container.

7.5 Presentation

30 white capsules packed in a 300 ml cylindrical white container with a lid and packaged in a single carton.

7.6 Disposal and handling of product

All unused medication should be disposed of in accordance with local regulatory authority.

8. Holder of certificate of registration

FoodGrown™©
371 Angus Crescent
Northlands Business Park
North Riding
Gauteng
South Africa

9. Registration Number

Still to be allocated

10. Date of first authorisation

Still to be allocated

11. Date of review

New

12. Reference: https://naturalmedicines.therapeuticresearch.com/

APPLICANT DETAILS:

FoodGrown™©
371 Angus Crescent
Northlands Business Park
North Riding
Gauteng
South Africa

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